IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 06-310-GMS

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION UNDER FED. R. CIV. P. 12(b)(6) TO DISMISS PLAINTIFF MERCK & CO., INC.'S COMPLAINT FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

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TABLE OF CONTENTS

INTRODUCTION 1

NATURE AND STAGE OF THE PROCEEDINGS 1

SUMMARY OF ARGUMENT 2

STATEMENT OF FACTS 4

ARGUMENT 9

I. THE 12(b)(6) STANDARD 9

II. MERCK'S COMPLAINT FAILS TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED 10

A. To Avoid Dismissal Merck Must State Facts Demonstrating That Teva USA Committed "Fraud Upon the Court" 10

B. Merck's Allegations That Teva USA Withheld Documents Describing Beagle Studies Fail to State a Claim for "Fraud Upon the Court" 11

1. Merck Has Not Pleaded a "Fraud" of Any Kind 11

2. Merck Has Not Pleaded a "Fraud Upon the Court" 13

C. Merck Has Not Alleged That Any Court Was Deceived 16

D. Merck's Complaint Shows That Merck Could Have Made the Argument It Alleges Was Concealed 18

CONCLUSION 19

TABLE OF AUTHORITIES

Cases

Appling v. Orrick, Harrington & Sutcliffe,
340 F.3d 769 (9th Cir. 2003) 14, 15

Broyhill Furniture Indus., Inc. v. Craftmaster Furniture Corp.,
12 F.3d 1080 (Fed. Cir. 1993)..... 14, 15, 16

Conley v. Gibson,
355 U.S. 41 (1957)..... 9

Fisher Bros. Sales, Inc. v. United States,
46 F.3d 279 (3d Cir. 1995)..... 16-17

General Motors Corp. v. New A.C. Chevrolet, Inc.,
263 F.3d 296 (3d Cir. 2001)..... 16

Gleason v. Jandrucko,
860 F.2d 556 (2d Cir. 1988)..... 11, 14, 15, 16

Herring v. United States,
424 F.3d 384 (3d Cir. 2005)..... 2, 11

Herring v. United States,
No. 03-CV-5500, 2004 U.S. Dist LEXIS 1854 (E.D. Pa Sept. 10, 2004) 9

In re Rockefeller Center Properties, Inc. Securities Litigation,
311 F.3d 198 (3d Cir 2002)..... 12, 13

King v. First American Investigations, Inc.,
287 F.3d 91 (2d Cir. 2002)..... 17

Merck & Co. v. Teva Pharmaceuticals USA, Inc.,
288 F. Supp. 2d 601 (D. Del. 2003)..... 1, 7

Merck & Co. v. Teva Pharmaceuticals USA, Inc.,
395 F.3d 1364 (Fed. Cir. 2005)..... 1

Merck & Co. v. Teva Pharmaceuticals USA, Inc.,
Civil Action No. 04-939 (GMS) 8

Morse v. Lower Merion Sch. Dist.,
132 F.3d 902 (3d Cir. 1997)..... 16

Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.,
836 F.2d 173 (3d Cir. 1988) 9

United States v. Beggerly,
524 U.S. 38 (1998) 11, 15, 16

Rules

Fed R. Civ. P. 60(b) ..... *passim*

Fed. R. Civ. P. 12(b)(6) 9

Fed. R. Civ. P. 9(b) 2, 13

INTRODUCTION

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") submits this brief in support of its motion under Fed. R. Civ. P. 12(b)(6) to dismiss plaintiff Merck & Co., Inc.'s ("Merck") complaint for failure to state a claim upon which relief can be granted. Merck's complaint purports to plead a claim for "fraud on the court" and seeks to reopen the judgment in a patent infringement case that Merck lost in the Federal Circuit. Even accepting Merck's largely false allegations as true, it cannot prevail, and the complaint must be dismissed.

NATURE AND STAGE OF THE PROCEEDINGS

This action stems from an earlier litigation in this Court between the same parties. In that case, Teva USA had filed an amendment to an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic equivalent to Merck's Fosamax drug product, and Merck alleged that the use of that proposed product would infringe its U.S. Patent No. 5,993,329 ("the '329 patent"). That patent claims administering the compound alendronate (the active ingredient in Fosamax) once a week at a dosage strength seven times the daily dose. (Complaint, D.I. 1 at ¶ 25.)

Merck sued to enforce the '329 patent. Teva USA stipulated to infringement, and following a bench trial, Judge Farnan found the asserted claims of the '329 patent not invalid and enforceable. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 288 F. Supp. 2d 601 (D. Del. 2003) (D.I. 1, Ex. F). The Federal Circuit reversed, however, holding the asserted claims invalid as obvious over the prior art. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005) (D.I. 1, Ex. I). The Federal Circuit issued its mandate on April 28, 2005. On May 2, 2005, this Court entered

judgment against Merck pursuant to the mandate. More than a year later, on May 10, 2006, Merck filed this action against Teva USA under Fed R. Civ. P. 60(b), seeking (1) relief from the judgment entered by this Court, or (2) an injunction against Teva USA from asserting any estoppel based on the Federal Circuit's decision. (D.I. 1 at ¶¶ 60, 64.) Teva USA submits this motion under Fed. R. Civ. P. 12(b)(6) in lieu of an answer.

SUMMARY OF ARGUMENT

To obtain relief from the Federal Circuit's judgment in under Rule 60(b), Merck must prove that Teva USA committed "fraud upon the court." *Herring v. United States*, 424 F.3d 384, 389 (3d Cir. 2005). In this circuit, such a showing requires proof of an intentional fraud by an officer of the court, directed to the court, and that the court was, in fact, deceived. *Id.* at 390. Even if they are assumed to be true, the facts Merck alleges cannot support such a claim. Merck alleges that Teva USA committed "fraud" by criticizing at trial preclinical studies disclosed in Merck's '329 patent that involved the administration of alendronate to beagles, while at the same time not producing in discovery a patent application (U.S. Patent Provisional App. No. 60/433,685) ("the '685 application" (D.I. 1, Ex. J)) filed by Teva USA's Israeli parent corporation, Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), which was not a party to the case. The '685 application describes an entirely different preclinical study from that described in the '329 patent. The only common denominator is that both studies involve administration of alendronate to beagles. As near as Teva USA can discern, Merck's theory is that Teva USA's original criticism was not a criticism of Merck's experimental design, but instead was a blanket indictment of the use of beagles, and its later employment of the same species and breed in an unrelated context somehow impeaches

that criticism. Since this impeachment allegedly was not available to Merck at trial, the Federal Circuit[1] was unable to appreciate the profound nature of Merck's beagle experiments and discounted them. Finally, according to Merck, if only the Federal Circuit had known the full story of Merck's beagles, it would have held the patent claims valid instead of invalid.

Assuming for the purposes of this motion that Teva Ltd.'s statements about its own beagle experiments in fact contradict Teva USA's criticism during the litigation of Merck's beagle studies (which they do not), and that Teva USA was obligated to produce the studies to Merck but chose not to (which is not true), Teva USA's actions cannot, as a matter of law, be found to constitute "fraud on the court." Merck does not allege facts showing that Teva USA or its attorneys committed a fraud, and it does not allege facts showing that any fraud was intentionally directed to the district court (or any appellate court), or that the district court (or any appellate court) was deceived. Finally, the complaint itself shows that the bogus impeachment argument was available to Merck in the district court and the Federal Circuit, but Merck did not make it. Accordingly, because Merck's complaint does not state a claim upon which relief can be granted, it should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

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[1] Although Merck contends that the district court was deceived, it does not explain how that deception can be reconciled with the fact that the court ruled in Merck's favor. *See* 288 F. Supp. 2d 601. (D.I. 1, Ex. F.)

STATEMENT OF FACTS

Although for purposes of this motion Teva USA will concede the facts of the complaint, that complaint is nevertheless replete with falsehoods and half truths. Exposing merely a few of them provides some insight into the nature of Merck's tactics.

First, Merck's entire complaint rests on the allegation that Teva USA did not provide discovery that it was obligated to provide. Merck relies on the Requests for Production ("RFP") that it served on Teva USA, the only defendant in the case. In particular, Merck relies on RFP 49, in which it requested "[a]ll documents and things relating to the research and development of alendronate and alendronate formulations or any other pharmaceutically active bisphosphonate and its formulations." (D.I. 1 at ¶ 20; *id.*, Ex. B at 17.) As Merck's complaint states, definition "I" of its RFPs sought to include Teva Ltd. in the definition of "Teva," notwithstanding that Teva Ltd. was not a party, and had never been served with any sort of judicial process. (D.I. 1 at ¶ 20; *id.*, Ex. B at 4.)

Although Merck quotes freely from its own RFPs and argues that Teva USA failed to produce the documents they called for, Merck inexcusably did not include Teva USA's responses and objections to those requests. (Those responses are attached as Exhibit A hereto.) In fact, Teva USA made two objections, each of which made clear that Teva USA was not undertaking to search for documents such as the '685 application. First, Teva USA objected to the RFPs to the extent that they called for documents from

any entities other than Teva USA, and affirmatively committed to producing documents *only* from that entity:

> Teva[2] objects to definition I as overly broad to the extent it includes entities beyond Teva Pharmaceuticals, USA. For purposes of the document request, responsive documents in the possession, custody or control of Teva Pharmaceuticals, USA will be produced.

(Ex. A at 5.) The '685 patent application upon which Merck bases its complaint was filed by and is assigned to Teva Ltd., not Teva USA, and thus falls outside the scope of documents that Teva USA undertook to search for and produce. Merck could not have overlooked that objection at the time. If Merck disagreed with the appropriateness of that limitation, it was free to challenge it, either informally or by application to this Court. In addition, Merck could not have overlooked that objection when it filed its complaint in this case. Nevertheless, for the transparent purpose of misleading the Court, Merck did not include it in its complaint.

Another limitation that Merck knew about and could not have overlooked was Teva USA's objection to producing any documents relating to subjects other that the development of the once-weekly alendronate dosage forms that were the subject of Teva USA's ANDA:

> Teva objects to each document request to the extent it seeks the identification or production of documents relating to any bisphosphonate other than the weekly dose forms of alendronate that are the subject of Teva's October 23, 2000 and August 20, 2001 amendments to No. 75-710.

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[2] In its responses to Merck's RFP's, Teva USA made clear that it was using the term "Teva" to refer only to "Teva Pharmaceuticals USA, Inc."

(*Id.*) In other words, Teva USA informed Merck that it would only produce documents concerning the particular tablets that were the subject of Teva USA's ANDA. Merck does not allege that the '685 application meets that criterion. Instead, the application is directed to a highly experimental dosing regimen in which a vitamin D compound is administered to the patient first, and the alendronate tablet is administered later. The purpose of this regimen is to improve the "bioavailability" of the alendronate, i.e., the amount of drug that the body actually absorbs. (D.I. 1 at ¶ 40.)

Teva USA carried this objection over specifically to RFP 49, informing Merck that it would only produce documents relating to the weekly alendronate products that are the subject of ANDA No. 75-710, and even then only documents relevant to the issues in the lawsuit:

> Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to the General Objections, responsive documents relating to the weekly alendronate product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

(Ex. A at 24.) Merck never challenged this objection, either informally or by seeking judicial relief. Having accepted Teva USA's undertaking on the scope of the documents it would endeavor to produce, Merck cannot legitimately complain about the non-production of documents outside that undertaking.

Not only did Merck know that Teva USA would not search for and produce documents such as the '685 application, Merck knows that the beagle experiments disclosed in the '685 patent are not in any way inconsistent with Teva USA's litigation arguments about Merck's beagle experiments as described in the '329 patent. The

experiments have a completely different purpose and design, and a criticism of one is not an indictment of the other or of beagle experiments in general.

The '329 patent discloses a series of experiments apparently designed to examine the toxic effect of alendronate on the esophagi of beagles. In these experiments, the beagles were anesthetized, laid prone, and their esophagi bathed in solutions of alendronate for half an hour. (D.I. 1, Ex. A at col. 14, ll. 52-55.) The beagles were then killed and the esophagus of each animal removed for microscopic examination for ulceration and other damage. (*Id.* at col. 15, ll. 42-46.) Of course, alendronate is not administered to humans in this way. It is given as tablets, and Merck provides a complicated set of dosing instructions to patients and doctors to ensure minimal exposure of alendronate to the esophageal tissues. Those measures include taking the tablets before eating anything, drinking a full glass of water and remaining upright for half an hour after administration. 288 F. Supp. 2d at 621, 628.

At trial, Teva USA pointed out the obvious fact that the beagle experiments did not model human clinical experience. Teva USA argued that the experiments were therefore not relevant to the asserted claims of the '329 patent. (D.I. 1 at ¶ 29; *id.*, Ex. D at 45-46.) Teva USA's argument was easy to make, since it relied primarily on the testimony of Merck's scientists and experts, who agreed with Teva USA that the beagle experiments in the '329 patent were not relevant to human clinical experience with the administration of that drug. (*Id.*)

The studies in the '685 application are completely different from those in the '329 patent; they involved, *inter alia*, the administration of alendronate tablets to unanesthetized, fasted beagle dogs, followed by detection of alendronate in their urine to

determine the bioavailability of the drug. (D.I. 1, Ex. J at 8.) The purpose of the study – to determine if the "pre-dosing" of another compound improves alendronate bioavailability – is completely different, as is the methodology – measuring alendronate in the dog's urine instead of killing the dog and examining its esophagus for injury.

Merck's complaint itself makes clear that the '685 patent is not material. Teva Ltd. owns U.S. Patent No. 6,476,006 ("the '006 patent"), which describes a tablet construction for certain drugs, including alendronate. (D.I. 1, Ex. K at Ex. A.) It includes as Example 13 a discussion of the same type of study as Merck claims was "concealed" by the non-production of the '685 application. (*Id.* at col. 14, ll. 15-22.) Merck successfully moved to add the '006 patent to the trial record, and referred to it at length in its post-trial reply brief and on appeal. However, Merck never once mentioned Example 13, and never made an argument that the '006 patent was somehow inconsistent with Teva USA's criticism of Merck's beagle experiments. Thus, the same argument that Merck says Teva USA concealed was available all along, yet Merck never made it. That it did not demonstrates that the argument is bogus, and has been concocted for an illegitimate purpose.

Merck's complaint is transparently defective, and its defects become even more apparent under even a cursory examination of the underlying record. Merck's reasons for bringing such a case are likewise clear: to delay and prejudice another case between the parties. Merck's complaint refers to the pending case between the parties that involves the drug substance risedronate, another compound in the same class as alendronate, which is prescribed for the same indications. *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 04-939 (GMS). (D.I. 1 at ¶¶ 37-38.) This case is set for trial

August 28, 2006. Although Merck does not sell risedronate, it has licensed Procter & Gamble ("P&G") to do so under Merck's once-weekly patents, including claims of the '329 patent that were not asserted in the alendronate case and that therefore have not yet been declared invalid. Merck receives substantial royalties from P&G, and those royalties will immediately cease if Merck loses the pending case. That outcome is likely, since the issues largely overlap. In addition, if Teva USA goes to market with generic once-weekly risedronate tablets, it will compete with Merck's Fosamax on the basis of price, something that P&G does not do. Thus, Merck has every incentive to delay the resolution of the pending case, and this complaint is a transparent attempt to do so.

Merck should not be permitted to manipulate the courts in this way. Merck's complaint should be dismissed, and the risedronate case should go forward as scheduled.

ARGUMENT

I. THE 12(b)(6) STANDARD

Under Fed. R. Civ. P. 12(b)(6), a complaint should be dismissed for failure to state a claim upon which relief may be granted if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). A claim may be dismissed when the facts alleged and the reasonable inferences drawn from those facts are legally insufficient to support the relief sought. *Herring v. United States*, No. 03-CV-5500, 2004 U.S. Dist LEXIS 1854, at *8 (E.D. Pa Sept. 10, 2004) (citing *Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3d Cir. 1988)).

As the foregoing discussion makes clear, Merck's factual statements are false. Nevertheless, even if the complaint is true, it fails to state a claim that could support the relief Merck seeks.

II. MERCK'S COMPLAINT FAILS TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

A. To Avoid Dismissal Merck Must State Facts Demonstrating That Teva USA Committed "Fraud Upon the Court"

A party may bring a motion to seek relief from a judgment pursuant to Fed R. Civ. P. 60(b) under certain circumstances:

> On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; (4) the judgment is void; (5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) *not more than one year after the judgment*, order, or proceeding was entered or taken . . . .

Fed R. Civ. P. 60(b) (emphasis added). For example, a party may seek relief from a judgment by filing a motion under Rule 60(b)(3) alleging "fraud . . . , misrepresentation, or other misconduct of an adverse party" (called "fraud between the parties") within one year from the date of judgment. *Id.* After the one-year period expires, under what has been referred to as the "savings clause" of Rule 60(b), a party may bring "an *independent action* to relieve a party from a judgment, order, or proceeding, . . . or to set aside a judgment for *fraud upon the court*." *Id.* (emphasis added). Merck seeks relief under this

latter provision of Rule 60(b). Thus, unlike a motion brought within the year, an independent action must be based on a "fraud upon the court."

The "fraud upon the court" standard that must be met to support an independent action under Rule 60(b) is "narrower in scope" than "fraud between the parties" which will suffice to support a Rule 60(b)(3) motion filed within one year of judgment. *Gleason v. Jandrucko*, 860 F.2d 556, 558 (2d Cir. 1988) ("[T]he type of fraud necessary to sustain an independent action attacking the finality of a judgment is narrower in scope than that which is sufficient by timely motion."). Thus, Merck must prove more than a fraud on Merck. Independent actions are reserved for situations where a "grave miscarriage of justice" has occurred. *United States v. Beggerly*, 524 U.S. 38, 47 (1998).

The Third Circuit has articulated a demanding standard for determining whether a fraud upon the court has occurred that will support an independent action under Rule 60(b). To obtain relief, a party must prove: (1) an intentional fraud; (2) by an officer of the court; (3) which is directed to the court; and (4) that in fact deceives the court. *Herring v. United States*, 424 F.3d at 390. Further, the Third Circuit agrees with other circuits that a "fraud upon the court" requires the most egregious conduct directed to the court itself, and must be supported by clear and convincing evidence. *Id.* at 387.

B. Merck's Allegations that Teva USA Withheld Documents Describing Beagle Studies Fail to State a Claim for "Fraud Upon the Court"

1. Merck Has Not Pleaded a "Fraud" of Any Kind

Merck has not alleged facts which, if proved true, would demonstrate an *intentional fraud* by Teva USA's attorneys *directed to the court*. First, Merck does not even allege that Teva USA committed a fraud. A claim based on fraud must be pleaded

with "particularity." Fed. R. Civ. P. 9(b). That is, a complaint alleging fraud must set forth "the who, what, when, where, and how of the events at issue." *In re Rockefeller Center Properties, Inc. Securities Litigation*, 311 F.3d 198, 217 (3d Cir 2002). The particulars of Merck's pleadings do not add up to fraud.

Merck alleges that it requested certain documents from "Teva," and that "Teva" did not provide them. This scenario does not describe a fraud, because the crucial elements – a false representation and reliance on that representation – are missing. Merck alleges that it requested such documents, yet it nowhere alleges that Teva USA represented that it would produce them. Merck cannot make that allegation, because Merck knows that Teva USA not only never undertook to produce such materials; it in fact interposed timely objections to doing so, which Merck never challenged.

Merck's only attempt to plead a misrepresentation or a reliance is its citation of Teva USA's counsel's letter. (D.I. 1, Ex. C.) That letter is narrow, and responds to specific allegations in Merck's motion to compel. The letter states only that Teva USA had conducted a search of the files of those people involved with development of once-weekly alendronate. Merck alleges that the statement was "false," but recites no facts to support that allegation, nor does it allege any connection between the alleged false statements and the '685 application. Merck nowhere alleges that such a search was *not* conducted, or alternatively that a search was conducted and documents were in fact found in the search and then concealed. Nowhere does Merck allege that any of the people whose files were searched had a copy of the '685 application, or that any of them received a copy thereafter (indeed, since the '685 patent has nothing to do with Teva USA's alendronate products, it is not surprising that not even Merck has the temerity to

suggest that they did). A general or conclusory allegation that a statement is "false," does not meet the particularity requirement of Rule 9(b). *Rockefeller*, 311 F.3d at 216. Since Merck has not even pleaded a "fraud" of any sort, its complaint must fail.

2. Merck Has Not Pleaded a "Fraud Upon the Court"

Even if Merck's allegations can be tortured into a claim of fraud, at best they allege that Teva USA withheld documents from Merck that Merck believed to be relevant, while falsely representing that all such documents had been provided. Assuming further that the withheld documents were relevant (which they were not), and giving Merck's complaint the most charitable reading, at most Merck has stated facts demonstrating that Teva USA's action hindered Merck's ability to make a factual argument – that its beagle studies were more consequential than Teva USA asserted. As the complaint states, Teva USA's actions "deprived Merck" of the opportunity to "depose Teva's inventors" and "analyze Teva's data, experimental techniques, and laboratory information." (D.I. 1 at ¶ 46.)

The fatal flaw in Merck's allegations is that they do not allege that Teva USA made a single representation either to the district court or to the Federal Circuit that was false. Making false statements to Merck that undercut Merck's ability to argue about a factual issue in the case is at best a fraud on Merck – not on the Court – that is, a so-called "fraud between the parties." This "deprivation" is not an injury to the Court or to the Court's function, but instead an injury only to Merck. A fraud between the parties cannot support relief from the judgment in an independent action under Rule 60(b).

Furthermore, where, as here, the alleged fraud is directed to the adverse party and could have been uncovered through that party's diligence, it does not work a grave

miscarriage of justice and cannot justify reopening the judgment. *Appling v. Orrick, Harrington & Sutcliffe*, 340 F.3d 769, 780 (9th Cir. 2003). *See also Broyhill Furniture Indus., Inc. v. Craftmaster Furniture Corp.*, 12 F.3d 1080, 1085-86 (Fed. Cir. 1993) ("Fraud upon the court is thus typically confined to the most egregious cases, such as bribery of a judge or juror, or improper influence exerted on the court by an attorney, in which the integrity of the court and its ability to function impartially is directly impinged.") (citations omitted); *Gleason*, 860 F.2d at 559 ("Indeed, 'fraud upon the court' as distinguished from fraud on an adverse party is limited to fraud which seriously affects the integrity of the normal process of adjudication.").

Here, Teva USA's "fraud" could have been uncovered by Merck's diligence. For example, Merck could have challenged Teva USA's objections to its RFPs. Merck was unequivocally on notice through Teva USA's objections that it would not produce documents from Teva Ltd. in Israel or documents that related to products other than the specific weekly products identified in the ANDA. Merck never challenged Teva USA's objections and all of the materials that it now claims were improperly withheld are covered by them.[3] Merck's allegations that Teva USA withheld certain patents and patent applications do not amount to "fraud upon the court" and cannot support an

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[3] Once Teva USA objected to Merck's RFP's and the definitions stated therein, it was incumbent on Merck to challenge those objections. *Clinchfield Railroad Co. v. Lynch,* 700 F.2d 126, 132 n.10 (4th Cir. 1983) ("Once a party registers, by way of a timely response, an objection to a discovery request, 'the initiative rests with the party seeking their production to move for an order compelling it.'" (citing 4A James Wm. Moore *et al.*, Moore's Federal Practice ¶ 34.05[2] (2d ed. 1982)). Instead, Merck acquiesced.

independent action under Rule 60(b). *Appling*, 340 F.3d at 780; *Gleason*, 860 F.2d at 559.

Examples of situations in which an alleged "fraud" has not amounted to "fraud on the court" demonstrate why Merck's complaint, even if it states a claim for fraud, is insufficient. In *Beggerly*, the Supreme Court held that the government's failure to furnish relevant information and to make a thorough search of its records and make a full disclosure to the Court did not rise to a fraud upon the court that could support an independent action under Rule 60(b) for relief from a judgment. *Beggerly*, 524 U.S. at 46-47. In essence, that is all that Merck is pleading here – a failure by Teva USA to make a thorough search and disclose relevant documents. In *Gleason*, the Second Circuit found that perjury committed by a witness and withholding relevant evidence did not rise to the level of fraud upon the court that would sustain a separate action for relief from a prior judgment. *Gleason*, 860 F.2d at 557, 560. Merck nowhere alleges that any Teva USA witness committed a criminal act or was suborned to do so. In *Broyhill*, the Federal Circuit held that enforcing a patent obtained through inequitable conduct (where the patent was obtained by knowingly withholding material prior art from the Patent Office) "does not alone constitute one of 'the more egregious form of subversion of the legal process . . .'" and was thus not fraud upon the court. *Broyhill*, 12 F.3d at 1086-87 (citations omitted). In *Appling*, the Ninth Circuit concluded that non-disclosure or perjury by a party or a witness, does not, but itself, amount to fraud upon the court. *Appling*, 340 F.3d at 780. Again, Merck alleges a failure to provide discovery, not anything as fundamental an attack on the court's function as perjury.

Merck does not allege that Teva USA's lawyers created false documents for presentation to the Court or a government agency or that they suborned perjury, or the like. *See, e.g., Broyhill*, 12 F.3d at 1085-86. Instead, Merck alleges that Teva USA withheld documents concerning a beagle study that was not conducted in the same manner as the studies in the '329 patent and which Teva USA told Merck during the litigation it would not be producing. Teva USA's actions, which, even according to Merck, are orders of magnitude less egregious than the actions alleged in *Beggerly* (withholding relevant evidence), *Gleason* (perjury and withholding relevant evidence), and *Broyhill* (withholding material prior art from the Patent Office and enforcing a patent obtained through inequitable conduct) that were held *not* to constitute fraud on the court.

C. Merck Has Not Alleged that Any Court Was Deceived

Merck's complaint includes no allegation that if true demonstrates that any court was actually deceived by Teva USA's alleged withholding of the '685 application. Merck only alleges that the evidence Teva USA allegedly withheld "would have affected the ultimate outcome of the FOSAMAX® once-weekly case." (D.I. 1 at ¶¶ 24, 47.) This conclusory and speculative legal conclusion should not be credited. *See General Motors Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 333 (3d Cir. 2001) ("Conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss. While facts must be accepted as alleged, this does not automatically extend to bald assertions, subjective characterizations, or legal conclusions.") (citations omitted); *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) ("a court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss"); *Fisher Bros. Sales, Inc. v. United*

States, 46 F.3d 279, 286 (3d Cir. 1995) ("the fact that we must accept the plaintiffs' version of the facts as true does not mean that we must accept the plaintiffs' *characterization* of those facts") (emphasis in the original). Merck's speculative allegation that things somehow might have been different is nothing more than a "bald assertion"; it is not an allegation of specific facts that if true would demonstrate that this Court or the Federal Circuit was actually deceived.

The facts as set forth in the complaint do not support a finding that the district court was deceived. First, the district court never commented on the merits of Merck's beagle experiments. Moreover, Merck won in the district court because the court *rejected* Teva USA's arguments on the merits. Merck makes no attempt to explain how the court could be deceived by Teva USA and yet rule in favor of Merck. Moreover, the Federal Circuit simply noted that Merck's experiment had been "discredited at trial and disregarded by the district court." (D.I. 1, Ex. I at 1374.) The Federal Circuit's observation was certainly fair, as the testimony of Merck's witnesses, which is included in an exhibit to Merck's complaint, demonstrates. (*Id.*, Ex. D at 45-46.)

At most, Merck's allegations reflect the fact that Teva USA's attorneys successfully argued their version of the facts and their theory of the law of obviousness. That the Federal Circuit resolved the issues in Teva USA's favor does not mean that Teva USA committed a Fraud. *See King v. First American Investigations, Inc.*, 287 F.3d 91, 95-96 (2d Cir. 2002) (finding that the plaintiff's allegations that the defendant committed fraud on the court amounted to nothing more than complaining that the plaintiff disputed the defendant's version of the law and facts and thus were insufficient to state a claim for fraud on the court).

D. Merck's Complaint Shows that Merck Could Have Made the Argument It Alleges Was Concealed

Merck's own complaint includes facts sufficient to defeat its claim. It shows that the impeachment argument that Teva USA allegedly concealed was in fact available to Merck at all relevant times. After trial, Merck successfully moved to add Teva Ltd.'s '006 patent to the trial record (Merck's motion is D.I. 1, Ex. K, and the '006 patent is Ex. A to that motion.) The '006 patent discloses in Example 13 the same type of beagle bioavailability study that is described in the '685 application. (D.I. 1, Ex. K, at Ex. A, col. 14, ll. 16-23.) If Teva Ltd.'s use of beagles as a test animal impeaches Teva USA's criticisms of Merck, then Merck had the ammunition to make that argument before the district court, the Federal Circuit, and the Supreme Court, and would have done so. However, Merck *never* mentioned the beagle study disclosed in the '006 patent, much less attempted to undermine Teva USA's arguments with it. That Merck did not do so demonstrates the bankruptcy of its current complaint. The beagle studies in Teva Ltd.'s '685 application simply do not contradict Teva USA's arguments at trial, as Merck clearly recognized at the time, and there is no evidence that the court was deceived by Teva USA's actions. Merck's allegations that it did not have an opportunity to impeach Teva USA's arguments relating to Merck's beagle experiments are made in bad faith and cannot support an equitable claim of "fraud upon the court" under Rule 60(b).

CONCLUSION

For the foregoing reasons, Teva USA's motion to dismiss Merck's complaint for failure to state a claim upon which relief should be granted and the case dismissed.

Respectfully submitted,

YOUNG CONAWAY STARGATT & TAYLOR, LLP

May 31, 2006

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on May 31, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send e-mail notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on May 31, 2006, I caused a copy of the foregoing document to be served on the above-listed counsel of record by e-mail [mgraham@mnat.com] and hand delivery, and on the following non-registered participants in the manner indicated below:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 01-048 (JJF)
	)	
TEVA PHARMACEUTICALS USA, INC., and	)	
	)	
Defendant.	)	
	)	

TEVA PHARMACEUTICALS USA'S
RESPONSE TO MERCK'S FIRST SET OF DOCUMENT REQUESTS (1-60)

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Teva responds to Merck's First Set of Document Requests as follows.

Each response is subject to all objections as to competence, relevance, materiality, propriety and admissibility, and to any and all other objections on any grounds that would require the exclusion of any statements contained herein if such responses were asked of, or statements contained herein were made by, a witness present and testifying in court, all of which objections and grounds are expressly reserved and may be interposed at the time of the trial.

The following responses are based upon information and writings currently available and located by Teva and the responses given herein are without prejudice to Teva's right to supplement or to revise these responses if further investigation or discovery so indicates.

Teva's responses shall not be deemed to constitute admission (i) that any particular document or thing exists, is relevant, non-privileged, or admissible in evidence, or (ii) that any statement or characterization in Merck's Document Requests is accurate or complete. In

addition, willingness to produce documents in response to any particular request is in no way a concession that such documents exist, or that any such documents are within Teva's possession, custody or control.

GENERAL OBJECTIONS

Teva's specific responses to all Merck's document requests are subject to the following General Objections, which are incorporated by reference in each response.

General Objection 1

Teva objects to each document request that is inconsistent with or seeks to impose an obligation beyond that required by the Federal Rules of Civil Procedure taken together with the Local Rules of the District of Delaware.

General Objection 2

Teva objects to the production of any documents or things which are subject to the attorney-client or joint defense privilege or work product immunity. In due course, following a completion of production of documents, Teva will provide a log of documents withheld from discovery on the grounds of attorney-client privilege, work product immunity, or both ("Privileged Document Log"), in exchange for such a log from Merck. Any inadvertent disclosure of such information shall not be deemed a waiver of the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity.

General Objection 3

Teva objects to the identification or production of any documents or things dated or prepared after the filing date of the Complaint in this action as being overly broad and unduly burdensome.

General Objection 4

Teva objects to each document request that is vague, indefinite, overly broad, unduly burdensome, and/or oppressive because the burden on Teva to search for, gather and produce such documents, if any, far outweighs the relevancy of such documents, nor are such documents likely to lead to the discovery of admissible evidence.

General Objection 5

Teva objects to each request to the extent it seeks production of "all documents" responsive to the requested categories on the grounds that such request is overly broad, unduly burdensome, oppressive, and not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections, Teva will use reasonable diligence to locate documents in its own files, based on an examination of those files reasonably expected to yield responsive documents, or summary information to the extent it is available. As used in these responses, the phrase "all documents," or phrases of similar import, should be understood to mean those documents Teva and its counsel were able to locate using reasonable diligence and judgment concerning the whereabouts of responsive documents, or a summary of those documents.

General Objection 6

Teva objects to each document request to the extent it seeks the identification or production of documents or things that are in the public domain and therefore of no greater burden for Merck to obtain than for Teva.

General Objection 7

Teva objects to each document request to the extent it seeks the identification or production of any and all documents and things that are otherwise producible but which contain confidential or proprietary information, except as provided by the District of Delaware local rules

or pursuant to a Protective Order entered in this case.

General Objection 8

Teva objects to the production of the following categories of documents on the grounds that the requests seeking these categories are overly broad, unduly burdensome, and not relevant to the subject matter of this litigation nor reasonably calculated to lead to the discovery of admissible evidence: (I) documents filed in this action and copies of communications between attorneys in this litigation; (ii) documents relating to settlement negotiations; (iii) duplicative or cumulative documents; and (iv) documents already in the possession of Merck.

General Objection 9

Teva objects to each document request to the extent it seeks the identification or production of third party documents that are covered by a third-party confidentiality agreement.

General Objection 10

Teva reserves the right to mask or delete materials from any document or thing that it produces to the extent that such materials are not responsive to any of Merck's requests, not relevant to the subject matter of this action, or not reasonably calculated to lead to the discovery of admissible evidence. Teva also reserves the right to mask or delete materials that are protected from disclosure by the attorney-client privilege, attorney work-product doctrine and/or otherwise immune from discovery.

General Objection 11

Teva objects to each document request to the extent it seeks the identification or production of any document relating to any FDA filing other than ANDA No. 75-710. Teva further objects to each document request to the extent it seeks identification or production of documents relating to ANDA No. 75-710 that are not relevant to this action.

General Objection 12

Teva objects to each document request to the extent it seeks the identification or production of documents relating to any biphosphonate other than the weekly dose forms of alendronate that are the subject of Teva's October 23, 2000 and August 20, 2001 amendments to ANDA No. 75-710 .

General Objection 13

Teva objects to each document request to the extent it seeks information relating to Teva's activities outside the United States, including legal proceedings or any efforts to seek marketing approval in a country other than the United States.

General Objection 14

Teva objects to each document request to the extent it seeks information relating to U.S. Patent Nos. 5,358,941, 5,681,590, 5,849,726, 6,008,207 and 6,090,410. Merck has withdrawn U.S. Patent No. 5,681,590 from this lawsuit, and has indicated it may withdraw U.S. Patent Nos. 5,358,941, 5,849,726, 6,008,207 and 6,090,410 from this lawsuit as well. If Merck decides not to withdraw these patents, Teva will withdraw this objection.

General Objection 15

Teva objects to each document request to the extent it seeks information relating to the manufacture of any of the ingredients in the alendronate formulations that are the subject of ANDA No. 75-710.

General Objection 16

Teva objects to definition I as overly broad to the extent it includes entities beyond Teva Pharmaceuticals, USA. For purposes of the document request, responsive documents in the possession, custody or control of Teva Pharmaceuticals, USA will be produced.

General Objection 17

Teva objects to definition BB, except for purposes of the document request

General Objection 18

Teva objects to the use of the term "defendants" in each of the document requests in which it appears because it is confusing. There is only one defendant in this lawsuit, Teva Pharmaceuticals U.S.A., and Teva will interpret the term accordingly.

General Objection 19

Teva objects to the use of the term "formulation [s]" in each of the document requests in which it appears because it is ambiguous. Teva will interpret this term to mean pharmaceutical formulations, i.e. active ingredients mixed with a pharmaceutically acceptable carrier.

General Objection 20

Teva objects to the use of the term "Defendants' certification" in each of the document requests in which it appears because it is confusing and ambiguous. Teva will interpret this term to mean the Teva's certifications relating to the weekly alendronate sodium product that is the subject of ANDA No. 75-710.

General Objection 21

Teva objects to each of the document requests to the extent they seek documents that have been produced in *Merck v. Teva*, Civ. Action No. 00-035 (JJF). By agreement of the parties, documents produced in that lawsuit will be deemed produced in this lawsuit.

RESPONSES TO DOCUMENT REQUESTS

Document Request No. 1

All opinions, legal or otherwise, relating to the validity, invalidity, infringement, non-infringement, enforceability, non-enforceability, liability, or license (either express or implied) to Defendants for any of the patents-in-suit or any other affirmative defense.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 2

All documents and things, including correspondence with counsel, relating to the validity, invalidity, infringement, non-infringement, enforceability, non-enforceability, liability, or license (either express or implied) to Defendants for any of the patents-in-suit or any other affirmative defense.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 3

All documents and things relating to patent clearances, freedom to operate opinions or other mechanisms to avoid infringement or willful infringement by Defendants of any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 4

All opinions, legal or otherwise, relating to the validity of the patent term extension or the patent term restoration of the '077 patent.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 5

All documents and things, including correspondence with counsel, relating to validity of the patent term extension or the patent term restoration of the '077 patent to Defendants.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 6

All documents and things relating to any policies or practices of Defendants concerning patent clearances, freedom to operate opinions or other mechanisms to avoid infringement or willful infringement by Defendants of the patents of others.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 7

All Abbreviated New Drug Applications filed by Defendants with the FDA for alendronate formulations or other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 8

All supplements and amendments to Abbreviated New Drug Applications filed by Defendants with the FDA for alendronate formulations or other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 9

All documents and things relating to or constituting correspondence or other communications, including but not limited to draft documents and correspondence, among Defendants and/or between Defendants and/or any other person and any foreign or domestic regulatory agency including, but not limited to, the FDA or a foreign counterpart concerning alendronate or any other pharmaceutically active biphosphonate.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 10

All documents and things relating to the patent certifications made by Defendants as part of an Abbreviated New Drug Application alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 11

All documents and things relating to Defendants' decision to file an Abbreviated New Drug Application alendronate formulations or any other pharmaceutically active biphosphonate formulations, including, but not limited to, the timing of the filing, the cost for the filing, and any cost or benefit analysis.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 12

All documents and things relating to the timing, schedule, timetable or projection of approval of Defendants' Abbreviated New Drug Application for alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 13

All documents and things relating to any labeling, promotion, advertising or claims by Defendants for alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to activities in the U.S. regarding the weekly alendronate sodium product that is the subject of ANDA 75-710 will be produced.

Document Request No. 14

All documents and things relating to Defendants' decision for file a patent certification as part of an Abbreviated New Drug Application for alendronate formulations or any other pharmaceutically active biphosphonate formulation.

Response

See response to request no. 10.

Document Request No. 15

All documents and things relating to FDA notification of "tentative approval"of the 'Abbreviated New Drug Application for Defendants' alendronate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium amendments to ANDA No. 75-710 will be produced.

Document Request No. 16

All documents and things relating to the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 17

All documents and things relating to the first awareness of the patents-in-suit by Defendants.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 18

All documents and things created before the filing of this suit concerning or constituting any prior art search relating to any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 19

All prior art that Defendants contend supports an allegation that any claim of the patents-in-suit is invalid.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 20

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are not, and/or will not be, infringed by Defendants.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 21

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are unenforceable.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 22

All documents and things forming the basis of, or relating to, any and all defenses pleaded by Defendants that any claim of the patents-in-suit is invalid.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 23

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as lacking a written description.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 24

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as the specification does not enable the claims.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 25

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as indefinite.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 26

All documents and things forming the basis of, or relating to, Defendants' certification

that any of the patents-in-suit are invalid as lacking utility.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 27

All documents and things forming the basis of, or relating to, Defendants' Certification that any of the patents-in-suit are anticipated by the prior art.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 28

All documents and things forming the basis of, or relating to, Defendants' certification that any of the patents-in-suit are invalid as obvious in light of the prior art

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 29

All documents and things relating to the April 21, 1997 patent term restoration of the '077 patent under 35 U.S.C. § 156.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 30

All documents related to Defendants' patent certification and Notice of Patent Certification for Abbreviated New Drug Applications for alendronate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium formulations that are the subject of ANDA No. 75-710 will be produced.

Document Request No. 31

All documents and things relating to any legal or administrative proceedings concerning the manufacture, importation, sale, and/or offer for sale of pharmaceutical formulations of alendronate or any other pharmaceutically active biphosphonate in the U.S. by Defendants or any other person.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product that is the subject of ANDA No. 75-710 will be produced.

Document Request No. 32

All documents and things concerning any indemnification and/or insurance provided to, received, or granted by Defendants against or for the infringement of any of the patents-in-suit.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 33

All documents and things relating to Defendants' production or attempted production of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request as overly broad and burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 34

All documents relating to research and development of manufacturing processes for alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 35

All documents and things relating to or comprising communications among Defendants and/or between Defendants and any other person concerning the design, development, testing, structure, function and/or operation of manufacturing facilities for the production of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 36

All documents and things relating to U.S. or foreign lawsuits, pending or previously resolved, or investigations regarding Defendants' production of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 37

All documents and things relating to any manufacture, importation, sale, and/or offer for sale of pharmaceutical formulations of alendronate or any other pharmaceutically active biphosphonate in the U.S. by Defendants or any other person.

Response

Teva objects to this request as overly broad and burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 38

All documents and things relating to any supply agreement for alendronate or any other pharmaceutically active biphosphonate.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 39

All documents and things constituting or relating to negotiations between Defendants and suppliers or potential suppliers of alendronate or any other pharmaceutically active biphosphonate.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 40

All documents and things relating to any desire, consideration or need by Defendants to obtain or not obtain a license under any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 41

All documents and things constituting or relating to licenses and/or agreements for alendronate or any other pharmaceutically active biphosphonate among Defendants and/or between Defendants and any other person.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 42

All documents and things related to licensing agreements among Defendants and/or between Defendants and any other person for the production, distribution or sale of alendronate formulations or any other pharmaceutically active biphosphonate formulations

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 43

All documents and things concerning marketing or whether to market alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any

other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 44

All documents and things relating to market share and market potential for alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 45

All documents and things relating to the dollar amounts expended by Defendants or any other person for the promotion of alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 46

All documents and things relating to all forms of promotions for or marketing of alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country by Defendants or any other person.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 47

All documents and things created after January 1, 1993, relating to any market survey, market analysis, sales projections or forecast of customer demand with respect to alendronate formulations or any other pharmaceutically active biphosphonate formulations in the U.S. or any other country.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, responsive documents relating to the weekly alendronate sodium product which is

the subject of ANDA No. 75-710 will be produced to the extent they are relevant to this lawsuit.

Document Request No. 48

All documents and things relating to any communications to or from Defendants' sales forces, agents, dealers, representatives, distributors, the press, or any news wire service relating to this lawsuit, and/or any of the patents-in-suit.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 49

All documents, and things relating to research and development of alendronate and alendronate formulations or any other pharmaceutically active biphosphonate and its formulations.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to the General Objections, responsive documents relating to the weekly alendronate product which is the subject of ANDA No. 75-710 will be produced to the extent they are relevant to the issues in this lawsuit.

Document Request No. 50

Two hundred alendronate tablets for each dosage form produced by Defendants for the

purpose of obtaining FDA approval.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to this and the General Objections, Teva will produce one hundred tablets of each of the weekly alendronate sodium product dosage forms that are the subject of ANDA No. 75-710.

Document Request No. 51

All documents and things relating to any tests comparing Merck's alendronate product with the alendronate product that Defendants produced.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 52

Any samples of Merck products that contain alendronate or any other pharmaceutically active biphosphonate that have been tested or examined by Defendants or any persons working on their behalf.

Response

Teva objects to this request as overly broad and unduly burdensome and is neither relevant to any issue in this lawsuit nor reasonably calculated to lead to the discovery of

admissible evidence.

Document Request No. 53

All documents and things relating to any testing performed using Merck's alendronate product.

Response

Teva objects to this request because it is overly broad and unduly burdensome in that it calls for documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence.

Document Request No. 54

All documents and things relating to Defendants' knowledge of Merck's activities in the research, patenting, development, manufacture, use or sale of any pharmaceutical formulation of alendronate or any other pharmaceutically active biphosphonate.

Response

Subject to the General Objections, responsive documents will be produced.

Document Request No. 55

All documents and things Defendants contemplate introducing at trial.

Response

Teva objects to this request as premature.

Document Request No. 56

All documents and/or things relating to any experts Defendants contemplate calling at trial, including but not limited to the educational and technical training of each expert and any publications authored by such expert.

Response

Teva objects to this request as premature.

Document Request No. 57

All documents and things, including but not limited to organizational charts, showing identity and job titles of employees since January 1, 1993 to the present for all of Defendants' divisions and/or subsidiaries involved in the research, development, production, design, manufacture or sale of alendronate formulations or any other pharmaceutically active biphosphonate formulations.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections and the General Objections, documents, documents sufficient to describe Teva's organization to the extent it relates to the weekly alendronate sodium product that is the subject of ANDA No. 75-710 will be produced.

Document Request No. 58

All documents and things setting forth Defendants' document retention and/or destruction policies.

Response

Teva objects to this request to the extent it is overly broad and unduly burdensome in that it encompasses documents that are not relevant to any issue in this lawsuit, and is not reasonably calculated to lead to the discovery of admissible evidence. Subject to these objections and the General Objections, responsive documents will be produced.

Document Request No. 59

All documents and things relating to or constituting applications by Defendants to obtain regulatory approval for alendronate or any other pharmaceutically active biphosphonate in a foreign country.

Response

See General Objection 12.

Document Request No. 60

Two grams of each ingredient in the alendronate tablets produced by Defendants for the purpose of obtaining FDA approval.

Response

Teva objects to this request because it is overly broad and unduly burdensome. Subject to this and the General Objections, Teva has already produced a two gram representative sample of the active ingredient in the alendronate product that is the subject of ANDA 75-710 in *Merck*

v. Teva, Civil Action No. 00-035 (JJF) .

YOUNG CONAWAY STARGATT
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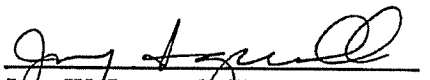

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CERTIFICATE OF SERVICE

I, Josy W. Ingersoll, Esquire, hereby certify that I caused copies of the foregoing document to be served on April 19, 2002 upon the following counsel of record:

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